

REMARKS

Claims 1, 5, 17, 20, and 24-25 and 27 are pending in the subject application. Claim 26 was canceled. Claims 1, 5 and 17 have been amended to delete the phrase "tumor gene determinant." No new matter is raised by these claim amendments.

Accordingly, claims 1, 5, 17, 20, and 24-25 and 27 are presented for examination on the merits.

Objections of the specification

The Examiner maintained the rejection of including the Serial Number for the prior application. Applicants disagree. The prior application was incorporated by reference throughout the specification as originally filed. See page 13 of the specification as filed. At the time of the filing, Applicants had not received the U.S. Application Serial Number for the application that was filed on November 20, 2001, as the pending application was filed on December 3, 2001, exactly thirteen days after the filing of the application that is 09/988,784. Therefore, in the absence of this information, the Applicants included the filing date information for the 09/988,784 in the specification. As previously noted, since the application was incorporated by reference at the time of the application, with the caveat that the only thing missing was the serial number, Applicants amended paragraph one of the specification to recite the appropriate Serial Number that was provided to us by the USPTO on January 2002. Additionally, the incorporation by reference language on page 13 was contained in the original specification. Again, this page of the specification was amended to recite the appropriate U.S. Application serial number referenced. Accordingly, applicant respectfully requests withdrawal of this ground of objection.

**Rejection of claims 1 and 5 under
of 35 U.S.C. §112, Second Paragraph - Written Description**

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the claimed subject matter.

The term "tumor gene determinant" was used in the specification as a generic term to include expression of certain genes present in tumors. In the effort to expedite prosecution, claims 1 and 5 have been amended to remove the recitation of "tumor gene determinant," thus rendering this ground of rejection moot. Accordingly, applicants request withdrawal of this ground of rejection.

**Rejection of claims 1, 5, 17, 24 and 27 under
of 35 U.S.C. §112, First Paragraph - Written Description**

Claims 1, 5, 17, 20, and 24-25 and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. In particular, the examiner alleges that the claimed invention lacks a correlation between a primary and metastatic tumor for EGFR and that

“[o]ther than the marker TS, one of skill in the art would not find such correlation” thus requiring undue experimentation to practice the claimed method.

Applicants disagree for the following reasons. The assertion that the specification must provide a correlation between the primary and metastatic tumors of the claimed tumor gene determinant before one of skilled in the art could determine the treatment of the metastatic tumor is contrary to the teaching of the specification. The present invention provides a method to determine an appropriate chemotherapeutic regimen for treating metastatic tumors based upon the level of tumor gene expression from a patient derived primary tumor sample. (See, for example, page 22 of the specification).

In particular, the present invention provides a method to determine the level of EGFR expression from a patient derived primary tumor sample. For example, uncorrected gene expression for EGFR and normalizing UGE with known relative EGFR expression levels can be calculated using the equations as provided in Example 3 of the specification. Additionally, on page 29 of the specification, the determination of the corrected relative ECFR expression is provided.

Further, Applicants have adequately provided in the specification that expression levels between primary tumors and metastatic tumors are similar. In particular, the specification provides proof of principle of the method as demonstrated by the detection of TS expression in primary tumors and metastatic tumors. This method that includes TS expression detection in primary tumors exemplifies the method for one species; there is no need to provide examples for every species. Moreover, the claims only require measuring primary samples to determine a chemotherapeutic regimen for treating a metastatic tumor based on the primary tumor expression level. Therefore, one skilled in the art can performed the claimed method without undue experimentation.

Applicants submit that the claimed method is adequately described in the specification to enable one skilled in the art to practice the method. Accordingly Applicants respectfully request withdrawal of this ground of rejection.

CONCLUSION

The Commissioner is hereby authorized to charge Deposit Account No. 11-0600 for the fees for the three-month extension of time. The Office is further authorized to charge any additional fees or credit any over payments under 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 11-0600.

The Examiner is invited to contact the undersigned at 202/220-4258 to discuss any matter in this application.

Respectfully submitted,

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